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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,627	02/18/2004	John C. Reed	66821-276	5834

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Cathryn Campbell
McDERMOTT, WILL & EMERY
4370 La Jolla Village Drive, Suite 700
San Diego, CA 92122

EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	PAPER NUMBER
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/782,627	REED ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-34* is/are pending in the application.

4a) Of the above claim(s) *6-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20070316*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The response filed February 7, 2007, is acknowledged and has been entered.

2. The election with traverse filed October 26, 2006, is acknowledged and has been entered.

Applicant has elected the invention of Group I, claims 2-5, insofar as the claims are drawn to a nucleic acid molecule, or complement thereof, comprising at least 20 contiguous nucleotides of the polynucleotide sequence set forth in SEQ ID NO: 1, which encodes a polypeptide having the amino acid sequence set forth in SEQ ID NO: 2.

3. Claims 2-34 are pending in the application. Claims 6-34 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 26, 2006.

4. Claims 2-5 are currently under prosecution.

Election/Restrictions

5. At page 6 of the response filed October 26, 2006, Applicant has traversed the propriety of the restriction and election requirement, which is set forth in the Office action mailed September 26, 2006.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

Applicant has remarked that though the different inventions are patentably distinct, a thorough search of the subject matter of one invention will reveal art that is relevant to the examination of the other inventions; and as such, Applicant has asserted that searching more than one of the inventions would not constitute a serious burden.

The Examiner disagrees with Applicant's assertion. As explained in the preceding Office action, the search required to consider claimed directed to any one of

the different inventions is not the same, nor is it coextensive with the search that would be required to consider claims directed to any of the other inventions. Therefore, although a thorough search of the subject matter of one invention may well reveal art that is relevant to the examination of the other inventions, that search would not suffice to permit an examination of the claims directed to the other inventions. Consequently, it would be necessary to perform more than one search to examine claims directed to more than one invention; and having to perform more than one search would in fact constitute a serious burden.

Accordingly, restriction and election requirement is deemed proper and therefore made FINAL.

Information Disclosure Statement

6. The information disclosure filed March 13, 2007, has been considered. An initialed copy is enclosed.

Oath/Declaration

7. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

(a) The declaration is defective because it not properly executed (i.e., John C. Reed did not write the date on the declaration on the date that it was signed).

(b) The declaration is defective because it does not identify the complete post office (mailing) address of John C. Reed; furthermore, although it identifies the address of the residence of Shinichi Takayama, it does not indicate that the post office (mailing) address of this inventor is the same.

The mailing addresses of the inventors may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

Specification

8. The specification is objected to because the use of improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

An example of such an improperly demarcated trademark appearing in the specification is Tween™; see, e.g., page 37, line 28.

Appropriate correction is required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., ™, ®), and accompanied by generic terminology. Applicants may identify trademarks using the "Trademark" search engine under "USPTO Search Collections" on the Internet at http://www.uspto.gov/web/menu/search.html.

9. The abstract of the disclosure is objected to because it is entitled "Abstract of the Invention", where it should be entitled "Abstract" or "Abstract of the Disclosure". Correction is required. See MPEP § 608.01(b).

Claim Objections

10. Claims 2-5 are objected to because the claims are directed to the subject matter of non-elected inventions. Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 2-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-5 are indefinite for the following reasons:

Claims 2 and 3 recite, "having a nucleotide sequence corresponding to [...]". The use of the term "corresponding to" renders the claims indefinite because it is unclear how, and then to what extent, the claims require the nucleotide sequence of the claimed nucleic acid to "correspond to" at least 20 nucleotides from SEQ ID NO: 1 (claim 2) or to correspond to a nucleotide sequence that encodes a functionally active BAG family protein. As a consequence the claims fail to delineate the subject matter that is regarded as the invention with the clarity and particularity to satisfy the requirements set forth under 35 U.S.C. § 112, second paragraph, so as to permit the skilled artisan to know or determine infringing subject matter.

Claims 3 and 5 recite, "a functionally active BAG family protein selected from the group [...]" of amino acid sequences, but it cannot be determined if the protein to which the claims are directed comprises or consists of the amino acid sequence set forth as part of the group. Thus, the claims fail to delineate the subject matter that is regarded as the invention with the clarity and particularity to satisfy the requirements set forth under 35 U.S.C. § 112, second paragraph, so as to permit the skilled artisan to know or determine infringing subject matter.

Claim 4 recites, "selected from the group [...]" of nucleotide seqeunces, but it cannot be determined if the claimed nucleic acid comprises or consists of the nucleotide sequence set forth as part of the group. Thus, the claim fails to delineate the subject matter that is regarded as the invention with the clarity and particularity to satisfy the requirements set forth under 35 U.S.C. § 112, second paragraph, so as to permit the skilled artisan to know or determine infringing subject matter.

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 2, 3, and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, "Written Description" Requirement (Federal Register; Vol. 66, No. 4, January 5, 2001). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

The claims are drawn to a genus of structurally and/or functionally varying nucleic acid molecules, which are merely described as comprising a nucleotide sequence that "corresponds to" or which is complementary to at least 20 nucleotides from SEQ ID NO: 1 (claim 2), which have a nucleotide sequence corresponding to or complementary to a nucleotide sequence that encodes a functionally active protein comprising or consisting of the amino acid sequence of SEQ ID NO: 2 (claims 3 and 4).

Giving the broadest reasonable interpretation of the claims, the claimed nucleic acid molecule comprises a nucleotide sequence that corresponds, but is not necessarily the same as any 20 contiguous nucleotides contained in SEQ ID NO: 1. The claimed nucleic acid molecule need not comprise a polynucleotide sequence of the full-length open reading frame, which the specification discloses encodes the amino acid sequence of SEQ ID NO: 2; and it need not comprise the full complement of the nucleic acid molecule comprising the entirety of the open reading frame encoding the amino acid sequence of SEQ ID NO: 2.

Contrary to any such indication, as recited, for example, in claim 3, most of these structurally varying nucleic acid molecules comprising mere fragments of at least 20 nucleotides of SEQ ID NO: 1 or the complements thereof are not reasonably expected to encode a functionally active protein comprising or consisting of the amino acid sequence of SEQ ID NO: 2.

Furthermore, again giving the broadest reasonable interpretation of the claims, the claimed nucleic acid molecule can merely have a nucleotide sequence that is complementary to a portion of the nucleotide sequence of SEQ ID NO: 1. Moreover, the claimed nucleic acid molecule need not comprise a polynucleotide sequence that is the full complement of the nucleotide sequence of SEQ ID NO: 1. Although the claimed nucleic acid molecule must have a polynucleotide sequence that is complementary to the nucleotide sequence set forth as SEQ ID NO: 1, this common structural feature of the nucleic acid molecules encompassed by the claim does not relate to any particularly identifying structural feature of the proteins encoded thereby, nor does it relate any particularly identifying functional feature of either the nucleic acid molecules or their translation products. The claimed nucleic acid molecule can be different or unrelated to the nucleic acid molecule encoding the polypeptide of SEQ ID NO: 2, provided it comprises a polynucleotide sequence that comprises at least a portion complementary to the nucleotide sequence of SEQ ID NO: 1. Accordingly, the claims are directed to a genus of nucleic acid molecules, which the members can vary markedly in both structure and function.

In contrast to claims 2, 3, and 5, claim 4 is directed to a nucleic acid molecule comprising or consisting of the nucleotide sequence of SEQ ID NO: 1. Accordingly, unlike claims 2, 3, and 5, claim 4 is directed to one or more nucleic acid molecules comprising the entirety of the nucleotide sequence of SEQ ID NO: 1, which is described as encoding a full length polypeptide having the amino acid sequence of SEQ ID NO: 2, as opposed to the much larger genus of structurally and/or functionally varying nucleic acid molecules to which the rejected claims are directed.

The specification only adequately describes the nucleic acid molecule of SEQ ID NO: 1, which comprises an open reading frame encoding a protein having the amino acid sequence of SEQ ID NO: 2.

However, the description of these few members of the claimed genus of nucleic acid molecules is not sufficient to meet the requirements of 35 USC § 112, first paragraph, since the genus embraces widely variant members and an adequate

description of such cannot be achieved by describing members, which are not representative of the genus.

Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description" Requirement (66 FR 1099-1111, January 5, 2001; hereinafter "Guidelines") states, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). "Guidelines" further states, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. Because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant had possession of the claimed invention at the time the application was filed.

In summary, as disclosed and claimed, the genus of nucleic acid molecules does not comprise members having a common, particularly identifying structural feature that correlates with a common functional feature shared by at least a substantial number of its members. As such, absent any of the factual evidence of an actual reduction to practice discussed above, the skilled artisan could not immediately envision, recognize, or distinguish at least a substantial number of the members of the claimed genus said at

least substantial number. Accordingly, the specification would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

15. Claims 2, 3, and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, **while being enabling for making and using** a substantially purified nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 1, which encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, a nucleic acid molecule comprising a nucleotide sequence that is the full complement of said nucleotide sequence of SEQ ID NO: 1, a substantially purified nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, a nucleic acid molecule comprising a nucleotide sequence that is the full complement of said nucleotide sequence encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, and a nucleic acid molecule *consisting of* a fragment of said nucleotide sequence of SEQ ID NO: 1 or said nucleotide sequence encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, **and while being enabling for making and using** any nucleic acid molecule encompassed by the claims, which is taught by the prior art, **does not reasonably provide enablement for making and using** the claimed invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

M.P.E.P. § 2164.01 states:

> The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors, which have been outlined in the Federal Circuit decision of *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), include, but are not limited to, the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed. See also *Ex parte Forman*, 230 USPQ 546 (BPAI 1986).

The amount of guidance, direction, and exemplification disclosed in the specification, as filed, would not be sufficient to enable the skilled artisan to use the claimed invention at the time the application was filed without undue and/or unreasonable experimentation.

As explained in the above rejection of the claims as failing to satisfy the written description requirement, the claims encompass a genus of nucleic acid molecules having widely varying structures and functions, which are merely described as having a short (i.e., 20 nucleotide sequence) portion of the nucleotide sequence set forth as SEQ ID NO: 1, or as having a sequence that is complementary to such a short portion.

Most of such structurally varying nucleic acid molecules are not expected to encode proteins comprising the amino acid sequence of SEQ ID NO: 2. Moreover, most are not expected to encode proteins having functions or activities that are similar to those of the polypeptide of SEQ ID NO: 2. Most are not expected to encode proteins that would be recognized as members of a family of functionally or structurally related proteins (e.g., the "BAG family of proteins).

Because the nucleic acid molecules, which encode such disparately related or unrelated proteins, have not been described, the claims amount to a mere invitation to the skilled artisan to make those nucleic acid molecules and then discover how the proteins encoded thereby might be used. The skilled artisan cannot know or predict

how such protein might be used; and so, then, such a need to elaborate upon the disclosure, so as to discover a use for the claimed invention falls well within the realm of undue and/or unreasonable experimentation.

Thus, the amount of guidance, direction, and exemplification set forth in the specification would only be sufficient to enable the skilled artisan to make and use a substantially purified nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 1, which encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, a nucleic acid molecule comprising a nucleotide sequence that is the full complement of said nucleotide sequence of SEQ ID NO: 1, a substantially purified nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, a nucleic acid molecule comprising a nucleotide sequence that is the full complement of said nucleotide sequence encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, and a nucleic acid molecule *consisting of* a fragment of said nucleotide sequence of SEQ ID NO: 1 or said nucleotide sequence encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 2.

Applicant is reminded that reasonable correlation must exist between the scope of the claims and scope of enablement set forth.

In deciding *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970), the Court indicated the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. "Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." *Genentech Inc. v. Novo Nordisk A/S*, 42 USPQ2d 1001, 1005 (CA FC 1997).

In conclusion, upon careful consideration of the factors used to determine whether undue experimentation is required, in accordance with the Federal Circuit decision of *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the amount of guidance, direction, and exemplification disclosed in the specification, as

filed, is not deemed sufficient to have enable the skilled artisan to use the claimed invention at the time the application was filed without undue and/or unreasonable experimentation.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claim 2, 3, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer Mannheim Biochemicals, 1994 Catalog (No. 1034 731/1006 924), page 93.

Claims 2, 3, and 5 are drawn to a substantially purified nucleic acid molecule comprising a nucleotide sequence corresponding to or complementary to at least 20 nucleotides of the nucleotide sequence of SEQ ID NO: 1.

For additional clarity, the claims are broadly but reasonably interpreted as encompassing nucleic acid molecules corresponding to or complementary to, but not necessarily the same as or fully complementary to any 20 nucleotides of SEQ ID NO: 1.

The Boehringer Mannheim catalog teaches a kit comprising a collection of random primers. The collection comprises a multitude of isolated and purified nucleic acid molecules (i.e., primers), each of which consists of 6 nucleotide residues. The collection comprises nucleic acid molecules having every possible 6-nucleotide sequence of the four different nucleotide residues (i.e., A, C, T, and G) of which DNA is comprised. Therefore, the kit comprises an isolated nucleic acid molecule consisting of a polynucleotide sequence that is, itself, fully complementary to any 20 nucleotides of

the polynucleotide sequence of SEQ ID NO: 1. Because the claims are drawn to nucleic acid molecules comprising a nucleotide sequence corresponding to or complementary to at least 20 nucleotides of the nucleotide sequence of SEQ ID NO: 1, such as a random primer contained in the kit, the disclosure of the kit and its contents by the prior art is anticipatory of the presently claimed invention.

18. Claims 2, 3, and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2001/0053519 A1.

U.S. Patent Application Publication 2001/0053519 A1 "n-mer arrays" comprising a solid support to which are attached all possible nucleic acid sequences of a given length, including, e.g., a 25-mer array; see entire document (e.g., page 10, paragraph [0101]).

The n-mer arrays (e.g., the array of 25-mers), which are disclosed by U.S. Patent Application Publication 2001/0053519 A1, comprise an isolated (substantially purified) nucleic acid molecule comprising a sequence that corresponds to or is complementary to at least 20 nucleotides of the polynucleotide sequence set forth as SEQ ID NO: 1.

19. Claims 2-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Takayama et al. (*Genomics*. 1996; **35**: 494-498).

The claims are drawn to a substantially purified nucleic acid molecule having the polynucleotide sequence set forth in SEQ ID NO: 1, which encodes the protein of SEQ ID NO: 2.

Takayama et al. teaches a substantially purified nucleic acid molecule having an identical polynucleotide sequence as that set forth in SEQ ID NO: 1; see entire document (e.g., 495, Figure 1).

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 2-5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,696,558 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

Claims 1 and 2 of the patent are drawn to a substantially purified nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 1 and a substantially purified nucleic acid molecule having a nucleotide sequence comprising nucleotides 46-1291 of SEQ ID NO: 1, respectively.

The claimed inventions are so substantially similar that for the most part, the claimed subject matter of the copending application anticipates the claimed subject matter of the instant application and any minor differences in the subject matter claimed

in the instant application would be seen as an obvious variation of the subject matter claimed in the copending application.

Conclusion

22. No claim is allowed.

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,539,094 A (of record; cited by Applicant) teaches a substantially purified nucleic acid molecule having a polynucleotide sequence that is identical to at least 20 nucleotides of the polynucleotide sequence set forth in SEQ ID NO: 1. U.S. Patent No. 5,650,491 A (of record; cited by Applicant) teaches a substantially purified nucleic acid molecule having a polynucleotide sequence that is identical to at least 20 nucleotides of the polynucleotide sequence set forth in SEQ ID NO: 1. WO 95/13,292 A1 (of record; cited by Applicant) teaches a substantially purified nucleic acid molecule having a polynucleotide sequence that is identical to at least 20 nucleotides of the polynucleotide sequence set forth in SEQ ID NO: 1.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stephen L. Rawlings, Ph.D.
Primary Examiner
Art Unit 1643

slr
April 10, 2007